K040275

FEB 27 2004

Summary of Safety and Effectiveness
Lyphochek® Hemostasis Control

1.0 Submitter

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Date of Summary Preparation

January 30, 2004

2.0 Device Identification

Product Trade Name:	Lyphochek® Hemostasis Control
Common Name:	Control Plasma Normal and Abnormal
Classifications:	Class II
Product Code:	GGC
Regulation Number:	21 CFR 864.5425

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Hemostasis Control
Bio-Rad Laboratories
Irvine, California

510(k) Number: K020878

4.0 Description of Device

Lyphochek® Hemostasis Control is prepared from human plasma with added purified biochemicals and preservatives. The control is provided in lyophilized form for increased stability.

5.0 Statement of Intended Use

Lyphochek® Hemostasis Control is intended for use as a quality control plasma to monitor the precision of laboratory analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Table 1 (below) contains comparison information of similarities and differences between the new Lyphochek Hemostasis Control and the currently marketed Lyphochek Hemostasis Control (K020878) to which substantial equivalence is claimed. The new Lyphochek Hemostasis Control is a tri-level product (Levels 1, 2 and 3) and contains D-dimer. The Lyphochek Hemostasis Control is a bi-level (Levels 1 and 2) product and does not contain D-dimer.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Lyphochek® Hemostasis Control (New Device)	Bio-Rad Lyphochek® Hemostasis Control (Predicate DeviceK020878)
Similarities		
Intended Use	Lyphochek® Hemostasis Control is intended for use as a quality control plasma to monitor the precision of laboratory testing procedures for analytes listed in the package insert.	Lyphochek® Hemostasis Control is intended for use as a quality control plasma to monitor the precision of laboratory testing procedures for analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human plasma based	Human plasma based
Storage (Unopened)	2-8°C until expiration date	2-8°C until expiration date
Reconstituted Vial Claim	8 hours at 2-25°C with the following exception: Protein S will be stable for 8 hours at 2- 8°C.	8 hours at 2-25°C with the following exception: Protein S will be stable for 8 hours at 2- 8°C.
Differences		
Levels	Levels 1, 2 and 3	Levels 1 and 2 Does not contain Level 3
Analytes	Contains: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin III (AT III) Thrombin Time (TT), Factor II, V, VII, VIII, IX, X, XI, XII, Protein S (Functional) Protein C (Functional), Plasminogen and D-dimer	Contains: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin III (AT III) Thrombin Time (TT), Factor II, V, VII, VIII, IX, X, XI, XII, Protein S (Functional) and Protein C (Functional), Plasminogen Does not Contain: D-dimer

7.0 Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Lyphochek® Hemostasis Control. Product claims are as follows:

2.1 Reconstituted Stability: All analytes will be stable for 8 hours at 2 -25°C with the exception of Protein S which will be stable for 8 hours at 2 - 8°C.

2.2 Shelf Life: Three years when stored at 2 - 8 °C

2.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 27 2004

Ms. Elizabeth Platt
Regulatory Affairs/Quality Assurance Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k040275
Trade/Device Name: Lyphochek Hemostasis Control
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for in vitro coagulation studies
Regulatory Class: II
Product Code: GGN
Dated: January 30, 2004
Received: February 5, 2004

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K040275

Device Name: **Lyphochek Hemostasis Control**

Indications for Use:

For use as a quality control plasma to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Analytes listed in the package insert:

- Antithrombin III (AT III)
- Activated Partial Thromboplastin Time (APTT)
- D-dimer
- Factor II
- Factor V
- Factor VII
- Factor VIII
- Factor IX
- Factor XI
- Factor XII
- Fibrinogen
- Plasminogen
- Protein C (Functional)
- Protein S (Functional)
- Prothrombin Time (PT)
- Thrombin Time (TT)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

510(k) K040275

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____